Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria™ for thrombolysis for lower extremity arterial and graft occlusions.

BIBLIOGRAPHIC SOURCE(S)

Levy JM, Duszak RL, Akins EW, Bakal CW, Denny DF, Martin LG, Van Moore A, Pentecost MJ, Roberts AC, Vogelzang RL, Kent KC, Perler BA, Resnick MI, Richie J, Becker G. Thrombolysis for lower extremity arterial and graft occlusions. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1041-54. [37 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Lower extremity arterial and graft occlusions

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Radiology
Surgery

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of thrombolysis in the treatment of lower extremity arterial and graft occlusions

TARGET POPULATION

Patients with lower extremity arterial and graft occlusions

INTERVENTIONS AND PRACTICES CONSIDERED

Transcatheter thrombolytic therapy

MAJOR OUTCOMES CONSIDERED

- Morbidity or mortality associated with lower extremity arterial and graft occlusions
- Improved care
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the American College of Radiology Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

Interventional Procedure: Lytic Therapy for Native Femoropopliteal or Graft Occlusion

Variant 1: Foot in severe pain, marbled on physical examination with marked motor impairment.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Diabetic hemorrhagic retinopathy	2	
• Hypertension, poorly controlled on medications	2	
• Thromboembolic MCA CVA 6 months ago	2	
• Coronary bypass 2 weeks ago	2	
• History of subacute bacterial endocarditis	2	
• Previous reaction to streptokinase	2	
• Cervical laminectomy 6 weeks ago	2	
• Pain began 24 hours ago	2	

Physical Examination		
• Absent popliteal and distal pulses	2	
• No extensor hallicus longus function	2	
• No capillary fill/refill	2	
Doppler		
• Arterial and venous signals absent	2	
Echocardiogram		
• Normal	2	
Angiogram		
• 4 cm SFA occlusion, popliteal reconstitution	2	
• Femoral-popliteal graft occlusion, NL inflow, 0-vessel runoff	2	
• Femoral-popliteal graft occlusion, 2-vessel runoff, distal emboli	2	
• Critical iliac stenosis, acute SFA occlusion	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 2: Graft placed 6 weeks ago.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Foot numbness	8	
• Extreme calf and foot pain for past 2 days	8	
• Current smoker	8	
• Stopped coumadin on own: prothrombin time (PT) = 12	8	
• On coumadin at time of admission: PT = 20	6	
• Bleeding ulcer within last 6 months	6	
• Hemorrhagic CVA within last months	2	
Physical Examination		
• Great toe dorsiflexion slightly weak	8	
• Light touch, pain sensation diminished	8	
• Slow capillary fill/refill	7	
• All dorsiflexion, proprioception absent	2	
• Absent capillary fill/refill	2	

• Foot cold and marbled	2	
Doppler		
• Both arterial and venous signals present	8	
• Arterial signal absent, venous signal present	8	
• Both arterial and venous signals absent	2	
Echocardiogram		
• Normal	8	
• Not obtainable on emergency basis	8	
Angiogram		
• Femoral-popliteal graft occlusion, no reconstitution	8	
• In situ graft occlusion, proximal fistulae from perforators	8	
• Femoral-popliteal graft occlusion clot in TP trunk too	8	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 3: No previous history of vascular procedures.

Presentations/Signs/Symptoms	Appropriateness	Comments

	Rating	
History		
• Progressive claudication, sudden change	8	
• Abrupt onset of foot coldness, numbness	8	
• History of myocardial infraction	8	
• Bleeding duodenal ulcer in remote past	8	
• Known abdominal aortic aneurysm	No Consensus	
• New atrial fibrillation	No Consensus	
• Nonhemorrhagic stroke 3 months ago	No Consensus	
Physical Examination		
• Absent popliteal + distal pulses on side	8	
• Blue toes, affected limb only	8	
• Blue toes in both limbs	4	
• 5-day old surgical incision, opposite groin	4	
• Bounding 2 cm wide contralateral, popliteal pulse	No Consensus	
Doppler		

• Popliteal arterial signal barely audible	8	
• Foot: venous Doppler audible, arterial absent	8	
• Foot: venous arterial Doppler absent	No Consensus	
Echocardiogram		
• Inferoapical hypokinesis	8	
• Left atrial thrombus	4	
• Left ventricular thrombus	4	
Angiogram		
• Left SFA occlusion, single tibial runoff vessel	8	
• Left popliteal occlusion, right popliteal aneurysm	6	
• Acute 5 cm popliteal occlusion, diffuse SFA	No Consensus	
• Abdominal aortic aneurysm, occluded left SFA	No Consensus	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 4: Change in limb status during therapy.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Nurse observed rigors	8	
• Pain became excruciating in last hour	8	
• New dysesthesia, but no neurologic findings	8	
Physical Examination		
• Temp = 39 degrees Celsius	8	
• Mild increase in sensory loss	8	
• Bleeding around sheath, no hematoma	8	
• Dorsiflexion weak at first, now absent	4	
• Leg indurated, tense; Doppler now absent	2	
• Leg swollen, tense anterolaterally	2	
Doppler and Angiogram		
• Venous and arterial signals still present	8	
• No change arterial signal, venous improved	8	
• Venous signal initially present,	4	

now absent		
• No angiographic change at 24 hours	2	
• Small nonoccluded thrombosis remains; pulse NL	No Consensus	
Laboratory Findings, Other Studies		
• Partial thromboplastin time (PTT) >100 seconds	8	
• Fibrin split products increased	6	
• Fibrinogen = 90 mg/dL	3	
• Myoglobin in urine, which is grossly pink	2	
• Hematocrit now 28, began at 40: stool heme negative	2	
• Urine output 100 cc in past 12 hours, CVP = 10	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 5: Acute worsening in clinical status of an outpatient.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Aortobifemoral graft 3 months	8	

ago, left limb occluded		
• Femoropopliteal graft 2 months ago now occluded	8	
• Femoro-posterior tibial graft 18 months ago, now occluded	8	
• 2nd fem-distal graft occluded; no saphenous available	8	
• Claudication worsened x 2 months, cold foot x 1 day	8	
• Above-knee PTFE femoropopliteal, painful calf x 1 day	8	
• Ax-bifemoral 2 years ago, foot painful, cold x 1 week	8	
• Third episode, same graft, patient smoking	No Consensus	
Physical Examination		
• Absent pulse in femoropopliteal graft	8	
• Ankle-brachial index (ABI) = 0.32	8	
• Slight decrease in pinprick sensation	8	
• Foot cool, pulseless, mild motor loss	7	

• Foot and lower leg marbled	2	
• Patient unable to move toes, forefoot	2	
Doppler		
• Signal absent in graft	8	
• Arterial + venous Doppler absent in foot	No Consensus	
• Velocities in graft; post-op 100, now 250 cm/second	No Consensus	
Echocardiogram		
• Normal	8	
Angiogram		
• 3 cm proximal femoropopliteal stump: 3-vessel runoff	8	
• Iliac artery and femoral-distal graft thrombosis	8	
• In situ graft, thickened valve, no thrombus	2	
• 99% iliac stenosis, patent graft	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 6: Gradual worsening in clinical status of an outpatient.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Above-knee PTFE femoropopliteal graft 1 year ago	8	
• Below-knee PTFE femoropopliteal graft 7 months ago	8	
• Below-knee in situ saphenous femoropopliteal	8	
• Reversed autogenous vein graft to peroneal	8	
• Femoral-posterior tibial graft 2 years ago: non healing ulcer	8	
• Femoral-popliteal graft occlusion; claudication at 1 block	8	
• Femoral-popliteal graft occlusion; 1/2 block claudication	8	
• Femoral-posterior tibial graft occluded, rest pain	8	
Physical Examination		
• Progressive atrophy, dependent rubor	8	
• Pulseless graft, venous Doppler heard in foot	8	

• Pulseless graft, surgical wound breakdown	3	
• Obese patient, partial femoropopliteal wound dehiscence	3	
• A-bifemoral limb occluded, right groin pseudoaneurysm	2	
Doppler		
• Venous only heard in foot	8	
• None heard	No Consensus	
Echocardiogram		
• Echocardiogram	8	
Angiogram		
• Complete occlusion both limbs of aorta-bifem	3	
• Femoropopliteal graft occlusion can't pass wire into occlusion	2	
• Femoropopliteal graft occlusion, no stump identified	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Variant 7: Native iliac arterial occlusion.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments

History		
• Progressive claudication only	8	
• Current heavy cigarette smoker	8	
• Nonhemorrhagic CVA 6 months ago	8	
• Stable angina	8	
• Claudication and impotence	8	
• Acute leg pain, foot weakness, and dysesthesia	7	
• Chronic arteriovenous malformations with bleeding in past 6 months	3	
• Contralateral claudication more limiting	2	
Physical Examination		
• Absent femoral pulse on symptomatic side	8	
• Absent pulses on symptomatic side; blue toes	8	
• Proprioception impaired; weak dorsiflexion	7	
• New right hemiplegia	2	
• Only good pulse; left axillary,	2	

both femorals absent		
• Hemoccult positive stool	2	
Doppler		
• Good arterial and venous signals in foot	8	
• Only venous signal audible in foot	8	
Echocardiogram		
• Unavailable	8	
• Vegetations seen on aortic valve	3	
• Left atrial thrombus	No Consensus	
Angiogram		
• Focal right iliac stenosis, long left iliac occlusion, normal aorta	8	
• Soft occlusion, guidewire passes easily	8	
• Firm occlusion, failed guidewire traversal	2	
• Diffuse disease of aorta, right iliac stenosis, left occlusion	2	
Appropriateness Criteria Scale		

1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate

Variant 8: Graft placed two years ago.

Presentations/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Foot numbness	8	
• Extreme calf and foot pain for past 2 days	8	
• Current smoker	8	
• Stopped coumadin on own; prothrombin time (PT) = 12	8	
• On coumadin at time of admission; PT = 20	8	
• Bleeding ulcer within last 6 months	7	
• Hemorrhagic CVA within last 3 months	2	
Physical Examination		
• Great toe dorsiflexion slightly weak	8	
• Light touch, pain sensation diminished	8	
• Slow capillary fill/refill	8	

• Absent capillary fill/refill	4	
• Foot cold and marbled	2	
• All dorsiflexion, proprioception absent	2	
Doppler		
• Both arterial and venous signals present	8	
• Arterial signal absent, venous signal absent	8	
• Both arterial and venous signals absent	No Consensus	
Echocardiogram		
• Normal	8	
Angiogram		
• No runoff vessels identified: graft occluded	8	
• Successful wire traversal; 2-vessel runoff	8	
• Proximal half of graft open, only 2 mm diameter	7	
• 2-vessel runoff, proximal stump, failed traversal	3	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9		

1=Least appropriate 9=Most appropriate

Summary

In most studies in the literature, variables have been analyzed for their effects on angiographic and clinical outcomes of thrombolytic therapy. The following conclusions derive from data on 3,121 infusions of thrombolytic agent for the treatment of lower extremity arterial and graft occlusions compiled from the references on the list. Very small studies without new information or conclusions have been eliminated from this analysis. The following are conclusions that may be drawn from the various studies in the evidence table prepared by the guideline developers to support the development of the guideline.

1. Local transcatheter thrombolytic therapy with urokinase is safe and efficacious in lysing thrombus that is causing lower extremity arterial or graft occlusion (initial thrombolytic success and clinical success in 60 to 100% of cases). Since the withdrawal of urokinase from the market, emphasis has shifted to recombinant tissue plasminogen activator as the thrombolytic agent of choice.
2. The success of thrombolytic therapy is not gender-dependent.
3. The vast majority of de novo arterial and graft occlusions encountered in clinical practice are thrombotic, not embolic.
4. Urokinase is a safer and more effective agent than streptokinase, and the proper role and dosage regimen for recombinant tissue plasminogen activator is evolving.
5. Although many investigators use concomitant intravenous heparin anticoagulation during thrombolytic therapy, its efficacy and safety have never been established. Conversely, there are large series in which systemic heparin was not used, and still there was no peri-catheter thrombus. In still other series that employed systemic heparin in some patients, but not in others, outcomes were not dependent upon heparin administration; full systemic heparin anticoagulation should be considered when the vascular occlusion is embolic or suspected to be embolic. Heparin should not be given in combination with recombinant tissue plasminogen activator. Heparin may be started at the completion of the thrombolytic therapy.
6. Some investigators have concluded, based upon intermediate term follow-up, that although thrombolytic therapy is often successful in iliofemoral grafts (or one limb of an aortobifemoral graft), the long-term results following lysis are inferior to those following surgery alone. Others have concluded that thrombolysis is safe and effective in supra-inguinal occlusions. These issues have not been resolved.
7. Acute ischemia category III patients are not suitable for a trial of thrombolytic therapy.
8. Pulse spray pharmacomechanical thrombolysis (PSPMT) may have a role; the question of increased risk of embolic complications has not been resolved.
9. Thrombolytic therapy is almost never definitive stand-alone therapy; rather, once lysis is complete, one may expect to find underlying anatomic conditions that are amenable to definitive therapy (surgery, percutaneous transluminal angioplasty, stent, atherectomy). Patients who have discernible underlying lesions that are then corrected, have a longer cumulative patency than those who do not receive definitive therapy after lysis.

10. One of the most important determinants of outcome is the number of patent runoff (tibial) vessels at the start of infusion: 2-3 vessel runoff portends a much better and more lasting result than does 0-1 vessel runoff; however, based upon the rates of limb salvage in the latter group (approximately 75%), a trial of thrombolytic therapy is still warranted in the face of 0-1 vessel runoff.
11. Two-year limb salvage and survival are each 85%.
12. In a prospective randomized trial of lysis versus surgery, 57 patients went to each group; 1-yr survival was 84% in the lysis group and only 58% in the surgery group. Differences were attributable to in-hospital cardiopulmonary complications (49% versus 16%), and the authors went on to state that lysis is suitable for iliac, femoropopliteal native arterial, and infrainguinal vein graft occlusions.
13. In the Surgery versus Thrombolysis for Ischemia of the Lower Extremity Trial, 30-day results were poorer in the group of patients randomized to lysis than in the group randomized to surgery, primarily due to problems associated with ongoing ischemia. However, in the subgroup of patients with occlusions <14 days old treated with lysis, amputation rates and lengths of stay were lower than for those treated surgically. Additionally, 6-month amputation-free survival was significantly better.

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate treatment and management of lower extremity arterial and graft occlusions with thrombolysis may improve overall survival and improve quality of life.

POTENTIAL HARMS

Complications of local thrombolytic therapy include: hemorrhage at puncture sites, remote hemorrhage, thromboemboli to small vessels in the extremity, revascularization syndromes including myoglobinuria (bad patient selection: acute ischemia category III) and compartment syndromes, and idiosyncratic reactions to the thrombolytic agent that may be interleukin-mediated. Bleeding complications are generally minor puncture site problems. If they become severe or if there is a serious hemorrhage at a remote site, the thrombolytic infusion

should be stopped. If heparin is being administered, it too must be stopped. Fresh frozen plasma or Amicar may be administered in extreme situations.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to transcatheter thrombolytic therapy include: irreversible ischemia, active internal bleeding within recent (e.g., past 3) weeks, Cerebrovascular accident within the past year, intracranial neoplasm, cranial or spinal surgery within the past 2 months, major thoracoabdominal surgery within the past 10 days, open heart surgery within the past 3 weeks, severe liver dysfunction, severe hypertension (uncontrolled), recent major trauma or cardiopulmonary resuscitation, history of emboli from a cardiac source, subacute bacterial endocarditis, severe coagulopathy, diabetic hemorrhagic retinopathy, lactation or pregnancy, inability to give informed consent, and inability to cross the entire thrombus with a guidewire. It should be noted that every one of the above contraindications is a relative one, and that given the appropriate circumstances, local (not systemic) thrombolytic regimens may still be instituted.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Levy JM, Duszak RL, Akins EW, Bakal CW, Denny DF, Martin LG, Van Moore A, Pentecost MJ, Roberts AC, Vogelzang RL, Kent KC, Perler BA, Resnick MI, Richie J, Becker G. Thrombolysis for lower extremity arterial and graft occlusions. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1041-54. [37 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 1999)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these American College of Radiology Appropriateness Criteria™.

GUIDELINE COMMITTEE

American College of Radiology Appropriateness Criteria™ Committee, Expert Panel on Interventional Radiology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Jonathan M. Levy, MD; Richard L. Duszak, Jr., MD; E. William Akins, MD; Curtis W. Bakal, MD; Donald F. Denny, Jr., MD; Louis G. Martin, MD; Arl Van Moore, Jr., MD; Michael J. Pentecost, MD; Anne C. Roberts, MD; Robert L.

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It is a revision of a previously issued version (Appropriateness criteria for thrombolysis for lower extremity arterial and graft occlusions. Reston [VA]: American College of Radiology [ACR]; 1996. 14 p.).

An update is not in progress at this time.

The American College of Radiology Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The next review date for this topic is 2004.

GUIDELINE AVAILABILITY

Electronic copies: Available (in Portable Document Format [PDF]) from the American College of Radiology (ACR) Web site.

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 28, 2002. The information was verified by the guideline developer on May 28, 2002.

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Date Modified: 11/15/2004